

SEAL NON ALCOHOL BASED HAND SANITIZER- benzalkonium chloride gel
ATLANTIC CARE CHEMICALS PRIVATE LIMITED

Disclaimer: Most OTC drugs are not reviewed and approved by FDA, however they may be marketed if they comply with applicable regulations and policies. FDA has not evaluated whether this product complies.

SEAL Non Alcohol based Hand sanitizer gel

Drug Facts

Purpose: Antiseptic

ACTIVE INGREDIENTS

Component

Benzalkonium chloride - 0.5 %

INACTIVE INGREDIENTS

Boro Glycerine, Carbomer, Triethanolamine, Methyl salicylate, Water, Citric acid, Vitamine E.

Use: Hand Sanitizer to help reduce microbes that potentially can cause disease. For use when soap and water are not available

When using this product: keep out of eyes, ears, and mouth. In case of contact with eyes, rinse eyes thoroughly with water.

Stop use and ask a doctor: if irritation occurs, please consult a doctor.

Do not use

- In children less than 2 months of age
- On open skin wounds.

Warning

- For external use only
- Keep out of Reach of Children

Directions

- Place enough product on hands to cover all surfaces. Rub hands together until dry.
- Supervise children under 6 years of age when using this product to avoid swallowing.

Other information

- Store between 15-30°C (59-86F)
- Avoid freezing and excessive heat above 40°C (104F)

Manufactured by:

Atlantic Care Chemicals. Pvt. Ltd
Industrial Development Plot,
Alappuzha, Kerala, India.

9001:2015

ISO CERTIFIED COMPANY



PASSION FOR INNOVATION

care@atlanticchemicals.com

www.atlanticchemicals.com

MADE IN INDIA

Packaging

SEAL		7724910445
Non Alcohol based Hand sanitizer gel		
Drug Facts		Purpose: Antiseptic
Use: Hand Sanitizer to help reduce microbes that potentially can cause disease. For use when soap and water are not available	ACTIVE INGREDIENTS	
When using this product: keep out of eyes, ears, and mouth. In case of contact with eyes, rinse eyes thoroughly with water.	Component	
Stop use and ask a doctor: if irritation occurs, please consult a doctor.	Benzalkonium chloride - 0.5 %	
Directions	INACTIVE INGREDIENTS	
• Place enough product on hands to cover all surfaces. Rub hands together until dry.	Boro Glycerine, Carbomer, Triethanolamine, Methyl salicylate, Water, Citric acid, Vitamine E	
• Supervise children under 6 years of age when using this product to avoid swallowing.		
Other information		
• Store between 15-30°C (59-86F)		
• Avoid freezing and excessive heat above 40°C (104F)		
Warning	Do not use	
• For external use only	• In children less than 2 months of age.	
• Keep out of Reach of Children	• On open skin wounds.	
Manufactured by:	9001:2015 ISO CERTIFIED COMPANY	
	Atlantic Care Chemicals. Pvt. Ltd Industrial Development Plot, Alappuzha, Kerala, India.	
	care@atlanticchemicals.com www.atlanticchemicals.com	Net Qty: 5 L (169.07 fl oz)
		MADE IN INDIA

SEAL NON ALCOHOL BASED HAND SANITIZER

benzalkonium chloride gel

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:77249-104
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
BENZALKONIUM CHLORIDE (UNII: F5UM2KM3W7) (BENZALKONIUM - UNII:7N6JUD5X6Y)	BENZALKONIUM CHLORIDE	5 g in 1 L

Inactive Ingredients

Ingredient Name	Strength
BOROGLYCERIN (UNII: U3LMU4AN21)	
CARBOMER HO MO POLYMER, UNSPECIFIED TYPE (UNII: 0 A5MM307FC)	
TROLAMINE (UNII: 9O3K93S3TK)	
METHYL SALICYLATE (UNII: LAV5U5022Y)	
WATER (UNII: 059QF0KO0R)	
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	
.ALPHA.-TO COPHEROL (UNII: H4N855PNZ1)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:77249-104-45	5 L in 1 CAN; Type 0: Not a Combination Product	05/15/2020	
2	NDC:77249-104-01	0.1 L in 1 BOTTLE; Type 0: Not a Combination Product	05/15/2020	
3	NDC:77249-104-02	0.2 L in 1 BOTTLE; Type 0: Not a Combination Product	05/15/2020	
4	NDC:77249-104-05	0.5 L in 1 BOTTLE; Type 0: Not a Combination Product	05/15/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	05/15/2020	

Labeler - ATLANTIC CARE CHEMICALS PRIVATE LIMITED (861499902)**Establishment**

Name	Address	ID/FEI	Business Operations
ATLANTIC CARE CHEMICALS PRIVATE LIMITED		861499902	manufacture(77249-104)

Revised: 5/2020

ATLANTIC CARE CHEMICALS PRIVATE LIMITED